



SYBRON DENTAL SPECIALTIES

SEP 21 2007

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.  
1717 West Collins Avenue  
Orange, CA 92867  
714) 516-7484 - Phone  
714) 516-7472 - Facsimile  
Colleen Boswell - Contact Person

Date Summary Prepared: June 2007

Device Name:

- Trade Name – FixaFloss
- Common Name – Rubber Dam Clamp
- Classification Name – Rubber dam clamp, 21 CFR § 872.6300

Devices for Which Substantial Equivalence is Claimed:

- The Hygenic Corp., *Wedjets*

Device Description:

The *FixaFloss* is a waxed dental floss assembled with 1 size and 1 color silicone conical resilient clamping element packaged as a one string product containing 20 resilient cones in a hygienic dispenser with an integrated cutting blade.

Intended Use of the Device:

The intended use of the *FixaFloss* is to be placed between teeth for the fixation of rubber dams.

Substantial Equivalence:

The *FixaFloss* is substantially equivalent to other legally marketed devices in the United States. The *FixaFloss* functions in a manner similar to and is intended for the same use as the *Wedjets* manufactured by The Hygenic Corp.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 21 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Colleen Boswell  
Vice President, Regulatory Affairs  
Sybron Dental Specialties, Incorporated  
1717 West Collins Avenue  
Orange, California 92867

Re: K071615  
Trade/Device Name: FixaFloss  
Regulation Number: 21 CFR 872.6300  
Regulation Name: Rubber Dam and Accessories  
Regulatory Class: I  
Product Code: EEF  
Dated: August 31, 2007  
Received: September 4, 2007

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

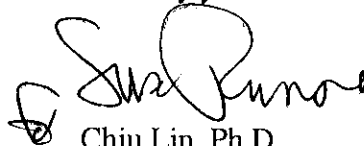
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071615

Device Name: FixaFloss

### Indications for Use:

The *FixaFloss* is a waxed dental floss with a silicone conical clamping element intended to be placed between teeth for rubber dam fixation.

Prescription Use ☒

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Rine  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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